K053519

510(k) SUMMARY

AUG 11 2006

1. Submitter's Identification:

Wuxi Yushou Medical Appliances Co., Ltd.
215#XiGang Road, DongbeiTang
WuXi City – JiangSu – 214191 - China
Telephone (262) 636-8957
Facsimile (262) 636-9760
Contact Timothy Llewellyn

Date Prepared: September 19, 2005 – Updated August 9, 2006

2. Device Name:

Trade/ Proprietary Name	Safety Syringe
Common Name	Syringe
Classification Name	Syringe, Antistick
Class	Class II, per 21 CFR § 880.5860
Product Code	MEG

3. Predicate Device(s):

BD Spring Based Syringe (K011103)

4. Description and Intended Use:

The Safety Syringe per (21 CFR § 880.5860) is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. Size variations are listed below.

The device's primary intended use is general purpose injection of fluids into, or withdrawal of fluids from the body, below the surface of the skin except for phlebotomy. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

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510(k) SUMMARY (cont'd.)

Following are the size variations.

Syringes Sizes
1cc
3cc
5cc
10cc
Pre-Tipped Syringes
1cc – 27g x 3/8"
1cc – 27g x ½"
1cc - 26 g x 3/8"
1cc - 25 g x 5/8"
1cc - 22 g x 1 1/2"

3cc - 25 g x 5/8"
3cc - 25 g x 1"
3cc - 23 g x 1"
3cc - 22 g x 3/4"
3cc - 22 g x 1"
3cc - 22 g x 1 1/2"
3cc - 21 g x 1"
3cc - 21 g x 1 1/2"
3cc - 20 g x 1"
3cc - 20 g x 1 1/2"

10cc - 21 g x 1"
10cc - 20 g x 1"

Needles Sizes
27g x 1/2"
25g x 5/8"
25g x 1"
25g x 1 1/2"
23g x 1"
22g x 1"
22g x 1 1/2"
20g x 1 "
20g x 1 1/2"
18g x 1"
18g x 1 1/2"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Wuxi Yushou Medical Appliances Company, Limited
C/O Mr. Gary Pond
CEO
Inter-Med, Incorporated
2200 Northwestern Avenue
Racine, Wisconsin 53404

Re: K053519
Trade/Device Name: Safety Syringes 1 cc, 3 cc, 5 cc, and 10 cc
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: July 17, 2006
Received: July 20, 2006

Dear Mr. Pond:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Julie H. McKee O.M.D.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K053519

Device Name: Safety Syringe

Indications for Use:

The device's primary intended use is general purpose injection of fluids into, or withdrawal of fluids from the body, below the surface of the skin except for phlebotomy. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence f CDRH, Office of Device Evaluation (ODE)

[signature]

Sign-Off)
n of Anesthesiology, General Hospital,
ion Control, Dental Devices

Number: K053519